BLA 125249/S-057

SUPPLEMENT APPROVAL

Kiniksa Pharmaceuticals (UK), Ltd.
c/o Kiniksa Pharmaceuticals Corp.
Attention: Liza Karpiak, MS, PharmD
Senior Director, Regulatory Affairs
100 Hayden Avenue
Lexington, MA 02421

Dear Dr. Karpiak:

Please refer to your supplemental biologics license application (sBLA) dated and received November 6, 2025, submitted under section 351(a) of the Public Health Service Act for Arcalyst (rilonacept) for injection.

This "Changes Being Effected" sBLA provides for updates to the BLA holder's and manufacturer's new address on the carton, vial label, USPI, PPI and IFU, removing the statement "No U.S. Standard of Potency" from the carton labeling, and relocation of the U.S. license number with the manufacturer's information.

APPROVAL & LABELING

We have completed our review of this sBLA. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible via publicly available labeling repositories.

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[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 125249/S-057**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, please contact Nowrin Kakon, Regulatory Business Process Manager, at Nowrin.Kakon@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Rapti Madurawe, PhD
Director
Division of Product Quality Assessment XVI
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert or Medication Guide
  - Instructions for Use
- Carton and Container Labeling

Rapti Madurawe

Digitally signed by Rapti Madurawe
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